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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,876	09/22/2003	Michael Johnson	1975/US	3615

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WILEY, REIN & FIELDING, LLP
ATTN: PATENT ADMINISTRATION
1776 K. STREET N.W.
WASHINGTON, DC 20006

EXAMINER

BERTRAM, ERIC D

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/668,876	Applicant(s) JOHNSON, MICHAEL	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action, or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 11/14/2006 have been fully considered but they are not persuasive. The Applicant's argue that Black does not teach an "arbitrarily-shaped electrode." According to paragraph [00147] of the applicant's specification, the "term 'arbitrarily-shaped' refers to the fact that the electrodes 1902 may be manufactured in any size and shape desired, and should not be taken to imply that the shape and/or size of the electrodes 1902 are random." This definition has to do with the method of manufacture of the electrode. However, since claim 15 is an apparatus claim, it is dealing with the exact structure of the catheter. Given its broadest reasonable interpretation, an "arbitrarily-shaped electrode" has no defined structure and can encompass an electrode of any size and shape, as long as it is desired by the user. Therefore, in the case of Black, an electrode 18 is disclosed that is in the desired size and shape of a ring electrode, clearly fitting the definition provided by the applicant in the specification.

2. The Applicant further argues that Black does not disclose that the electrode is "overmolded by a portion of the catheter." However, as admitted by the applicant on page 3 of the Remarks, Black does indeed disclose an overmolded portion that is subsequently removed through grinding. However, in this "intermediate " state, as referred to by Applicant, Black discloses each and every limitation found in independent claim 15. Applicant argues that by including a subsequent step, Black teaches away from the presently claimed invention. However, since Black is a 35 USC 102(b)

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reference, i.e. anticipatory reference, it is immaterial whether or not Black teaches a subsequent step or not; as long as each and every limitation in a claim is met, the application of a 35 USC 102(b) reference is considered proper (see MPEP 2131). Furthermore, the catheter defined in claim 15 is also in an "intermediate" state, as evidenced by claim 18, which further claims exposing a portion of the electrode.

3. Therefore, the 35 USC 102(b) rejections of claims 15, 17-23, 25-27, 29 and 30 are still considered proper. The 35 USC 103(a) rejections of claims 16, 24 and 28 are also still considered proper since the Applicant merely relied on the arguments presented against Black and discussed above.

Claim Objections

4. Claim 15 objected to because of the following informalities: In line 5 of the claim, it appears that "on" should be replaced with --one--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 15, 17-23, 25-27, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Black et al. (US 6,216,045, hereinafter Black). Black discloses a catheter for use in a medical procedure, including a catheter body 22 and a catheter tip 34 operably connected to the catheter body. Black further discloses arbitrarily-shaped electrodes 18 attached to the catheter, wherein the electrodes, along with the entire

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catheter assembly is overmolded (Col. 7, lines 5-11). Energy is delivered to the electrodes through wire conductors 20 (Col. 4, lines 3-17).

7. Regarding claims 17, 21-23, 25 and 26, Black discloses that the catheter body comprises a lumen tube 24 nested in jacket 23, wherein the wire conductors 20 are located on the exterior surface of the lumen tube (see figure 3). Black shows in figure 5 that the electrodes 18 must pass through the jacket 23 to contact the conductors.

8. Regarding claim 18, the electrodes must inherently be exposed from the overmold of the catheter to allow the electrodes to electrically stimulate the body (Col. 1, lines 5-10).

9. Regarding claims 19 and 20, Black discloses that the electrodes are composed of biocompatible, conductive material, specifically platinum (Col. 3, lines 40-45).

10. Regarding claims 27, 29 and 30, it is the Examiner's position that the wire conductors are inherently traces, given its broadest reasonable interpretation.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 16 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black. Black, as described above, discloses the applicant's basic invention with the exception of electrodepositing the electrodes and traces onto the catheter.

However, it would have been an obvious matter of design choice to modify Black by electro-depositing the traces and electrodes onto the catheter since, upon reviewing the specification, the applicant has not disclosed that electro-depositing the traces and electrodes solves any stated problem or is for any particular purpose, and it appears that the catheter would perform equally well no matter how the electrodes or the traces have been attached to the catheter.

14. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Black in view of Quackenbush (US 5,125,913). Black, as described above, discloses that applicant's basic invention, including a catheter comprising a tube along which wire is run. Black does not disclose, however, that the tube and wire are co-extruded.

Attention is directed to the secondary reference of Quackenbush, which discloses the use of co-extrusion when forming a medical catheter. Therefore, it would have been obvious to one of ordinary skill in that art at the time of the applicant's invention to modify the catheter of Black by co-extruding the tube and wire as suggested by Quackenbush because co-extrusion is a cheaper process since two steps can be completed in a single step.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

EDB